UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA

KATELYN WEILBRENNER, A MINOR AND DIANN COURTOY, INDIVIDUALLY AND AS NATURAL MOTHER AND NEXT FRIEND OF KATELYN WEILBRENNER, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Case No. 7:08-cv-23

TEVA PHARMACEUTICALS USA, INC.'S STATEMENT OF MATERIAL FACTS IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Local Rules of the United States District Court for the Middle District of Georgia, defendant Teva Pharmaceuticals USA, Inc. ("Teva") hereby submits this Statement of Material Facts in Support of its Motion for Summary Judgment. The following facts are undisputed and demonstrate that Teva is entitled to summary judgment.

A. Procedural History

1. Plaintiffs Katelyn Weilbrenner and DiAnn Courtoy ("Plaintiffs") allege that Ms. Weilbrenner developed the condition pseudotumor cerebri ("PTC") and subsequent vision loss as an adverse reaction to Teva's pharmaceutical product minocycline hydrochloride ("minocycline").

2. Minocycline is the generic form of the branded drug Minocin® and is approved by the United States Food and Drug Administration ("FDA") as an antibiotic commonly prescribed to treat bacterial infections, including acne.

3. Plaintiffs' Complaint seeks to hold Teva liable on one or more claims purporting to sound in: strict liability in tort or negligence, breach of express or implied warranty, negligent or innocent failure to warn, and negligent or innocent misrepresentation, concealment, or nondisclosure. (Compl. ¶ 14.) Plaintiffs also assert a claim for punitive damages. (Compl. ¶ 17.)

A. Alleged Ingestion and Injuries

4. On January 16, 2006, Plaintiff Katelyn Weilbrenner was prescribed the antibiotic minocycline hydrochloride by her primary care physician, Dr. Robert Hawes, for treatment of acne. (Compl. ¶ 4; Ex. A, Pl.'s Resp. Interrogs. 5.)

5. Dr. Hawes did not review or rely on Teva's minocycline labeling, or warnings contained therein, in making his decision to prescribe minocycline to Ms. Weilbrenner. (Ex. M, Hawes Dep. 66:11-15, 68:3-14.) Dr. Hawes also did not review any other sources regarding minocycline or Minocin®, including the Physicians' Desk Reference, at the time that he prescribed minocycline to Ms. Weilbrenner. (*Id.* at 68:18-22.)

6. On January 16, 2006, Plaintiffs filled a prescription for Teva's 100mg minocycline hydrochloride capsules. Plaintiffs refilled the prescription on February 28, 2006 with the same minocycline product. (Compl. ¶ 4.)

7. Ms. Weilbrenner claims that she began taking minocycline on January 16, 2006, took it regularly for approximately thirty days, and then sporadically until May 11, 2006. (Ex. B, Courtoy Dep. 102:2 – 9, 106:5 – 110:15.) Ms. Weilbrenner claims that she ingested a total of approximately 54 minocycline capsules. (*Id.* at 106:5 – 7.) Ms. Weilbrenner ceased taking minocycline no later than May 11, 2006. (Compl. ¶ 5.)

8. On or about April 24, 2006, Ms. Weilbrenner claims that she began experiencing severe headaches. (Compl. ¶ 5.)

9. On May 8 and May 9, 2006, Ms. Weilbrenner presented to her primary care physician and his assistant. (Compl. ¶ 5.)

10. On May 11, 2006, Ms. Weilbrenner was seen by an optometrist, Dr. Michael Hopkins, and an ophthalmologist, Dr. Terrance Croyle, and was diagnosed with optic disc edema, papilledema, and pseudotumor cerebri. (Compl. ¶ 5; Ex. C, Croyle Dep. 43:15 – 44:22, 51:15 – 52:17.)

B. Federal Regulation of Generic Drugs

11. The manufacture and sale of branded and generic prescription drug products in the United States is a highly regulated industry, under the jurisdiction of the FDA. The FDA draws its statutory authority as to the approval of manufacture and sale of drugs primarily from its enabling statute, the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., as amended by the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Amendments") (collectively, the "Food and Drug Act" or "FDCA"), and has promulgated regulations implementing such statutes, which may be found in pertinent part at 21 C.F.R. Part 314.

12. Under the United States' regulatory scheme, prescription drugs fall into two categories, branded drugs and generic drugs.

13. A branded drug (or "reference-listed drug") is one that has not yet been established or generally recognized by persons with relevant scientific training as safe and effective for the purposes or medical indications for which its use is intended. 21 U.S.C. § 312(p). The right to manufacture and market such a drug in the United States is secured through the filing of a New Drug Application ("NDA"). 21 U.S.C. § 355. In order to obtain

approval of a NDA, the applicant (innovator) must demonstrate the safety and efficacy of the drug for its intended indications to the satisfaction of the FDA, typically through the conduct of extensive clinical trials in humans.

14. Congress and the FDA have enacted statutory provisions and regulations to encourage the manufacture and marketing of the other category of drugs, known as generic drugs. Specifically, the Hatch-Waxman Amendments (codified at 21 U.S.C. § 355(j); 35 U.S.C. §§ 156, 271, 281), establish the current procedure for obtaining approval from the FDA to market and sell a generic drug, allowing the generic maker to submit an abbreviated NDA ("ANDA").

15. The requirements that a generic manufacturer must meet under the ANDA process are set forth in Section 505(j) of the Food and Drug Act, 21 U.S.C. § 355(j). The process begins with a requirement that the information not be new or innovative, but wholly derivative of information already provided by the innovator manufacturer. *See* 21 U.S.C. § 321(aa). An ANDA applicant is not required or expected to conduct clinical trials to establish the safety and efficacy of its drug. The Food and Drug Act and FDA's regulatory scheme contemplates that safety and efficacy will have been established by the pharmaceutical company who originally submitted the NDA for the counterpart branded drug. In contrast, the generic manufacturer is obliged only to conduct so-called "bioequivalency" studies, to establish that its dosage formulation of the generic product has the same pharmacological action in the human body as does the branded drug. If the generic version of the drug is shown to be "bioequivalent" to the branded drug, it is assumed to have the same safety and efficacy profile.

16. The labeling – that is, the prescribing information or package insert – of the generic drug may not deviate in any material respect from that of its reference listed drug. 21

U.S.C. § 355(j). But for differences relating to the fact of the product being manufactured by a different company, chiefly physical description, inactive ingredients and, perhaps, listing fewer indications for use, the generic manufacturer's labeling, including all statements as to Warnings, Precautions, Contraindications, Adverse Reactions, must adhere letter for letter to the language in the corresponding provisions of the labeling of the relevant reference-listed drug. 21 U.S.C. § 355(j).

17. An ANDA holder does not have the right to enhance warnings on the label for its product through the mechanism of 21 C.F.R. § 314.70(c)(6)(iii)(A), the so-called "Changes Being Effected Amendment" provision. This provision is, in the context of prescription pharmaceuticals, available only to NDA holders.

C. Teva's Minocycline Product and Labeling

18. In 1992, Teva's predecessor, Biocraft Laboratories, Inc. ("Biocraft"), first received approval of ANDA No. 63-009 for its 100 mg minocycline hydrochloride capsules. (Ex. E.) In 1996, Biocraft (together with Lemmon Company) formed the corporate entity Teva Pharmaceuticals USA, Inc., and Teva became owner of this ANDA for minocycline. (Ex. F.)

19. Teva's package insert for its minocycline hydrochloride capsules, in effect when Plaintiffs allege ingestion, warns in the Precautions and Adverse Reactions sections of the possible risk of PTC. The package insert also warns in the Precautions section of possible risk of permanent sequelae (Ex. H):

> **PRECAUTIONS**
> * * *
> Pseudotumor cerebri (benign intracranial hypertension) in adults has been associated with the use of tetracyclines. The usual clinical manifestations are headache and blurred vision. Bulging fontanels have been associated with the use of tetracyclines in infants. While both of these conditions and related symptoms usually resolve after discontinuation of the tetracycline, the possibility for permanent sequelae exists.

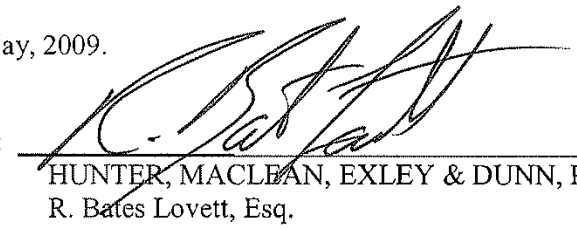
* * *

ADVERSE REACTIONS

* * *

Central Nervous System: Bulging fontanels in infants and benign intracranial hypertension (pseudotumor cerebri) in adults (see **PRECAUTIONS, General**) have been reported. Headache has also been reported.

Respectfully submitted this 5th day of May, 2009.

By: 

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